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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,776

12/29/2005

Toshihiro Kuroita

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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

10/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,776	Applicant(s) KUROITA ET AL.	
	Examiner LISA V. COOK	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☒ Claim(s) 8-13 is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Species Election***

1. Applicant's response to the Species Restriction mailed 7/11/08 is acknowledged (paper filed 7/25/08). In the response filed 7/25/08, Applicant elected Species I (claims 8-13) with traverse. Applicant has traversed the species restriction, contending that there would be no serious burden on the Office if the species were search together. In addition applicant argues that all the species (I, II, and III) are directed to a Dnak protein. The arguments have been carefully considered but not found persuasive because each of the species read on independent and distinct protein constructs which would produce independent and distinct compositions or sequence identification numbers. The instant disclosure identifies sequence identification numbers 1-17. These separate peptides bear distinct structural or biochemical properties as substantiated by the separate SEQ ID numbers and diverse composition configurations, therein having different binding epitopes for unique diverse compositions. **Therefore, each disclosed patentably distinct peptide sequence is considered a separate invention.** See Official Gazette 1232 OG 242(116) March 21, 2000. Therein the O.G. notice permits the examiner to examine up to ten nucleotide sequences per application based on the use of US PTO resources. Resources are now stretched to the limit, such that only one sequence should be searched per application.

2. The requirement is still deemed proper and is therefore made **FINAL**.

Art Unit: 1641

3. Claims 1-7 and 14-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traverse the restriction requirement in the reply filed on 7/25/08. Currently claims 8-13 are under consideration.

Priority

4. If applicant desires priority under 35 U.S.C. 120 to application number PCT/JP04/09785 filed 7/2/04 which claims benefit to foreign application number 2003-191081 filed in Japan on 7/3/03 (based upon previously filed applications), specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included.

If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. *If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.*

Art Unit: 1641

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application.

If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c).

The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional.

Art Unit: 1641

The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

5. The instant application should be updated to include application number PCT/JP04/09785 filed 7/2/04 which claims benefit to foreign application number 2003-191081 filed in Japan on 7/3/03.

Information Disclosure Statement

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered. For example see pages references listed through out the disclosure.

7. The information disclosure statements filed 3/20/06 has been considered as to the merits before First Action.

Art Unit: 1641

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. On page 1 line 25 a typo appears "caw", it should read "cow". Please correct.

II. The use of the trademarks has been noted in this application. (.i.e. TWEEN and SEPHADEX - see page 5 line 10, page 18 line 25, and page 34 line 20, for example). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Objections

9. Claim 8 is objected to as being in improper claim format. See 37 CFR 1.75. Claim 8 recites "The protein" while dependent claims 9-13 also recite "The protein". However, claim 8 should be directed to "A protein". Appropriate correction is required.

10. Claims 8-13 are objected to for utilizing the phrase "characterized by" and "composed of". It is suggested that the claims are written to read on "comprising" or "consisting of" in order to obviate this objection. See MPEP 2111.03 [R-3].

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 8-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 8-13 the term "derived" is a relative term, which renders the claim indefinite. Derived reads on not only the parent source (HSP70 family protein or Dnak protein) but also any product therefrom, thus the term is relative. The term "derived" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what the claim will encompass? Is the protein a modified Dnak protein or some other composition? It is suggested that the claim merely recite wherein said protein is a modified Dnak protein.

B. Claims 10-12 recite the limitation "obtained by" which is vague and indefinite because the instant claims are directed to a product. This phrase makes the claims ambiguous because it is not clear as to what the product will encompass. In particular, it is not clear if the claimed protein is intended to include the recited deletions or is directed to sequences obtained from the deleted compositions. Accordingly the metes and bounds of the claims can not be determined.

Art Unit: 1641

It is suggested that the “obtained by” language be replaced with “comprising” or “consisting of” in order to obviate this rejection. Appropriate correction is required.

C. Claims 10-13 are drawn to amino acid sequences and/or modification of a sequence which is not claimed. As such the claims are vague and indefinite because it is not clear what sequence is actually intended to be claimed. Although the claims recite a Dnak protein, an initial sequence for deletion (modification) and/or final sequence (actual) for the protein composition are not recited. The specification defines several sequences which have not been specifically claimed. Therefore one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is suggested that the actual modifications with reference to the sequence identification numbers be included in the claims in order to obviate the rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 8-13 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

13. Claims 8-13, as written, do not sufficiently distinguish over the claimed biomarker as it exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Human proteins are products of nature.

Art Unit: 1641

In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth sequence identification numbers 1 through 17 and therefore the written description is not commensurate in scope with the claims drawn to any and all protein compositions derived from an "HSP70 family protein" or a "Dnak protein". See claims and sequence listing filed 12/29/05.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is several from its enablement provision (see page 115).

With the exception of SEQ ID NOS: 1-17, the skilled artisan cannot envision the detailed structure of the encompassed protein compositions instantly claimed and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of a compound/seq.id/etc. by only their functional activity does not provide an adequate written description of the genus.

Art Unit: 1641

The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a sequence, falling within the scope of the claimed genus.

At section B(1), the court states that "An adequate written description ...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention" There is insufficient description in the disclosure to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Therefore only the isolated sequences identified as SEQ ID NOS:1-17, but not any and all protein compositions derived from an "HSP70 family protein" or a "Dnak protein" would meet the full breadth of the claims as required by the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1641

I. Claims 8-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Chesnokova et al. (Biochemistry, August 5, 2003, Vol42, No.30, Pages 9028-9040).

Chesnokova et al. disclose the Hsp70 molecular chaperone DnaK with deletions that produce three domains. Residues 1-388, 393-507, and 508-638 are produced and utilized to evaluate GrpE complex formations. See abstract, figure 2, Table 1, and pages 9037-9039.

II. Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (Journal of Biological Chemistry, 1996, Vol271., No.33, pages 19668-19674).

Zhang et al. disclose DnaK compositions including amino acids numbered 506-543. See figure 3, figure 5, and page 19673.

III. Claims 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Swain et al. (Biochemical Society symposium, 2001, No.68., pages 69-82).

Swain et al. disclose DnaK with deletions that produce a fragment comprising amino acids 387-552. See abstract, page 72, and page 78 for example.

IV. Claims 8-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang and Walker (Archives of Biochemistry and Biophysics, 8/15/98, Vol356, No.2, pages 177-186).

Zhang and Walker disclose DnaK fragments that include aa residues 384-638, 389-607, 386-561, and 607-638). See abstract, figure 5, and page 182.

Art Unit: 1641

16. For reasons aforementioned, no claims are allowed.

Remarks

17. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Boice et al.(Journal of Biological Chemistry, 1997, Vol.272, No.40, pages 24825-24831) teach the molecular structure of DnaK protein.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, can be reached on (571) 272-0806.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Remsen 3C-59
571-272-0816
9/25/08

/Lisa V. Cook/
Examiner, Art Unit 1641